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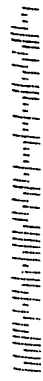
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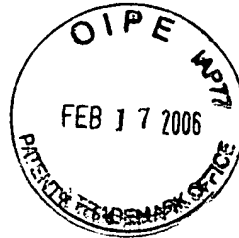


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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,083	11/26/2003	Illimar Altosaar	0109144.143 US1	5920

7590 01/13/2006
Jane M. Love, Ph.D.
HALE AND DORR LLP
300 Park Avenue
New York, NY 10022



EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/723,083

Applicant(s)

ALTOSAAR ET AL.

Examiner

Elizabeth F. McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4,6,7,9,10,12,14,16,17,19,20,22,24,26,27 and 29-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,4,6,7,9,12,14,16,17,19,22,24,26,27,29 and 31-35 is/are allowed.
- 6) ☒ Claim(s) 10,20 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>1/6/06</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/12/05</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Response to Amendment

The amendment filed October 20, 2005 has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10, 20 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "nucleotide sequence 55-435 of" with regard to SEQ ID NO: 1 does not find support in the application, as originally filed. Amendment of the claims to delete this phrase would overcome the rejection.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

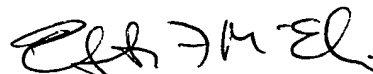
Art Unit: 1638

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM

Interview Summary	Application No.	Applicant(s)	
	10/723,083	ALTOSAAR ET AL.	
	Examiner	Art Unit	
	Elizabeth F. McElwain	1638	

All participants (applicant, applicant's representative, PTO personnel):

(1) Elizabeth F. McElwain. (3) _____

(2) Kristen Joslyn. (4) _____

Date of Interview: 03 January 2006.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____

Claim(s) discussed: 10,20 and 30.

Identification of prior art discussed: none.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Claims 10, 20 and 30 appear to contain new matter. Cancellation of claims would put the case in condition for allowance.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

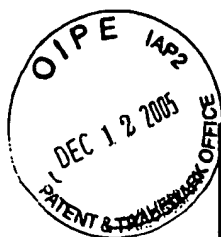
A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.



PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/B/PTO		Complete if Known			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/723083-Conf. #5920		
		Filing Date	November 26, 2003		
		First Named Inventor	Illimar ALTOSAAR		
		Art Unit	1638		
		Examiner Name	Elizabeth F. McElwain		
Sheet	1	of	3	Attorney Docket Number	0109144.00143US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A1	US-5,677,474	10-14-1997	Rogers, J. C.	ALL
	A2	US-5,889,189	03-30-1999	Rodriguez, R. L.	ALL

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
gm	C1	Aoyama and Chua, "A glucocorticoid-mediated transcriptional induction system in transgenic plants," The Plant Journal Vol. 11, No. 3, pp. 605-612 (1997)			
	C2	Brandstatter, I. and Kieber, J.J., "Two genes with similarity to bacterial response regulators are rapidly and specifically induced by cytokinin in Arabidopsis," The Plant Cell Vol. 10, pp. 1009-1019 (1998)			
	C3	Burgess, A.W., et al. "Purification and properties of bacterially synthesized human granulocyte-macrophage colony stimulating factor," Blood, Vol. 69, pp. 43-51 (1987).			
	C4	Caddick et al, "An ethanol inducible gene switch for plants used to manipulate carbon metabolism," Nature Biotech. Vol. 16, pp. 177-180 (1998)			
	C5	Cantrell, M.A., et al. "Cloning, sequence, and expression of a human granulocyte/macrophage colony-stimulating factor," Proc Natl Acad Sci USA Vol. 82, pp. 6250-6254 (1985).			
	C6	Cheng, X et al., "Rice transformation by Agrobacterium infection," In: Recombinant Proteins from Plants: Production and Isolation of Clinically Useful Compounds. (eds. C. Cunningham and A.J.R. Porter) Humana Press, pp. 1-9 (1998)			
	C7	Cheng et al., "Agrobacterium-transformed rice plants expressing synthetic CryIA(b) and CryIA(c) genes are highly toxic to striped stem borer and yellow stem borer," Proc Natl Acad Sci USA Vol. 95, pp. 2767-2772 (1998)			
	C8	Denecke et al, "Protein secretion in plant cells can occur via a default pathway," The Plant Cell, Vol. 2, pp. 51-59 (1990)			
	C9	Ernst, J.F., et al. "O-glycosylation and novel processing events during secretion of alpha-factor/GM-CSF fusions by Saccharomyces cerevisiae," Bio/Technology, Vol. 5, pp. 831-834 (1987).			
EL	C10	Gatz, C., "Chemical Control of Gene Expression," Ann. Rev. Plant Physiol. Plant Mol. Biol. Vol. 48, pp. 89-108 (1997)			
Examiner Signature	97 McElwain			Date Considered	1/6/06

Substitute for form 1449A/B/PTO				Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/723083-Conf. #5920
				Filing Date	November 26, 2003
				First Named Inventor	Illimar ALTOSAAR
				Art Unit	1638
				Examiner Name	Elizabeth F. McElwain
Sheet	2	of	3	Attorney Docket Number	0109144.00143US1

gm	C11	Jaeger, G.D., et al. "Boosting heterologous protein production in transgenic dicotyledonous seeds using Phaseolus vulgaris regulatory sequences," Nature biotechnology, Vol. 20, pp. 1265-1268 (2002).
	C12	James, E.A., et al., "Production and characterization of biologically active human GM-CSF secreted by genetically modified plant cells," Protein Express Purif, Vol. 19, pp. 131-138 (2000).
	C13	Kakimoto, T., "CKI1, a histidine kinase homolog implicated in cytokinin signal transduction," Science, Vol. 274, pp. 982-985 (1996)
	C14	Kaushansky, K., et al. "Role of carbohydrate in the function of human granulocyte-macrophage colony-stimulating factor," Biochemistry Vol. 26, pp. 4861-4867 (1987).
	C15	Kitamura, T., et al., "Establishment and characterization of a unique human cell line that proliferates dependently on GM-CSF, IL-3, or erythropoietin," J Cellular Physiol, Vol. 140, pp. 323-334 (1989)
	C16	Lee, F., et al. "Isolation of cDNA for a human granulocyte-macrophage colony-stimulating factor by functional expression in mammalian cells," Proc Natl Acad Sci USA Vol. 82, pp. 4360-4364 (1985).
	C17	Metcalf, D., "Control of granulocytes and macrophages: Molecular, cellular, and clinical aspects," Science Vol. 254, pp. 529-533 (1991).
	C18	Moonen, P., et al. "Increased biological activity of deglycosylated recombinant human granulocyte/macrophage colony-stimulating factor produced by yeast or animal cells," Proc Natl Acad Sci USA Vol. 84, pp. 4428-4431 (1987).
	C19	Murray et al., "Codon usage in plant genes," Nuc Acids Res. Vol. 17, pp. 477-498 (1989)
	C20	Okamoto, M., et al. "Amplification and high-level expression for human granulocyte-macrophage colony-stimulating factor in human lymphoblastoid Namalwa cells," BioTechnology, Vol. 8, pp. 550-553 (1990).
	C21	Quesniaux and Jones. "Granulocyte-macrophage colony-stimulating factor," In: The Cytokine Handbook, (ed. Angus T.W.) Academic Press pp. 637-670 (1998).
	C22	Saalbach, I., et al. "High-level expression of a single-chain Fv fragment (scFv) antibody in transgenic pea seeds," J. Plant Physiol. Vol. 158, pp. 529-533 (2001).
	C23	Salter et al, "Characterisation of the ethanol-inducible alc gene expression system for transgenic plants," The Plant Journal Vol. 16, No. 1, pp. 127-132 (1998)
	C24	Sardana et al., "Construction and rapid testing of synthetic and modified toxin gene sequences CryIA (b&c) by expression in maize endosperm culture," Plant Cell Reports Vol. 15, pp. 677-681 (1996)
	C25	Sardana R, et al. "Biological activity of human granulocyte macrophage colony stimulating factor is maintained in a fusion with seed glutelin peptide," Transgenic Research Vol. 11, No. 5, pp. 521-531 (2002).
	C26	Stoger, E., et al. "Cereal crops as viable production and storage systems for pharmaceutical ScFv antibodies," Plant Mol Biol., Vol. 42, pp. 583-590 (2000).
	C27	Tobias et al., "The N-end rule in bacteria," Science, Vol. 254, pp. 1374-1377 (1991)
	C28	Ulmasov, T., et al., "Aux/IAA proteins repress expression of reporter genes containing natural and highly active synthetic auxin response elements," The Plant Cell, Vol. 9, pp. 1963-1971 (1997)
	C29	Varshavsky, "The N-end rule: functions, mysteries, uses," Proc. Natl. Acad. Sci USA, Vol. 93, pp. 12142-12149 (1996)
	C30	Vitale, A., et al., "The role of endoplasmic reticulum in protein synthesis, modification and intracellular transport," Journal of Experimental Botany, Vol. 44, No. 266, pp. 1417-1444 (1993).
gm	C31	Wong, G.G., et al. "Human GM-CSF: Molecular cloning of the complementary DNA and purification of the natural and recombinant proteins," Science, Vol. 228, pp. 810-815 (1985).

Examiner Signature	ST MSL	Date Considered	1/6/06
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete If Known	
				Application Number	10/723083-Conf. #5920
				Filing Date	November 26, 2003
				First Named Inventor	Illimar ALTOSAAR
				Art Unit	1638
				Examiner Name	Elizabeth F. McElwain
Sheet	3	of	3	Attorney Docket Number	0109144.00143US1

Em	C32	Zheng, Z., et al. "5'distal and proximal cis-acting regulator elements are required for developmental control of a rice seed storage protein glutelin gene," The Plant Journal, Vol. 4, No. 2, pp. 357-366 (1993).	
Em	C33	Zheng, Z.W., et al. "The bean seed storage protein beta-phaseolin is synthesized, processed, and accumulated in the vacuolar type-II protein bodies of transgenic rice endosperm," Plant Physiol Vol. 109, pp. 777-786 (1995).	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	<i>EF McElwain</i>	Date Considered	1/6/06
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US1DOCS 5412889v1